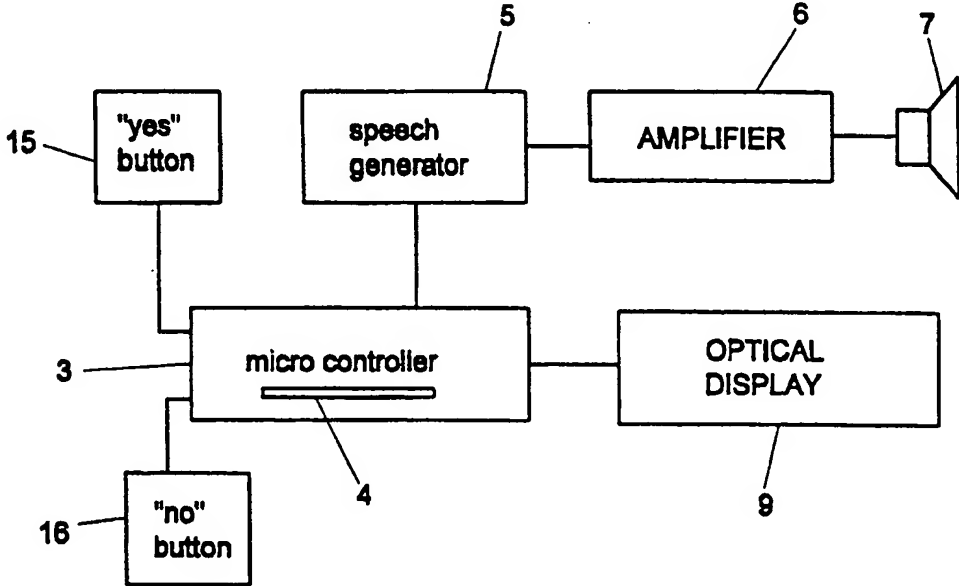




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/NL97/00315 <b>(22) International Filing Date:</b> 5 June 1997 (05.06.97) <b>(71)(72) Applicant and Inventor:</b> PALSMA, Harmen, Jacob [NL/NL]; Koninginnelaan 65D, NL-9717 BP Groningen (NL). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> BRUGTS, Jack [NL/NL]; Bredeborg 23, NL-9722 WK Groningen (NL). <b>(74) Agent:</b> SMULDERS, Th., A., H., J.; Vereenigde Octrooibureaux, Nieuwe Parklaan 97, NL-2587 BN The Hague (NL).		<b>(81) Designated States:</b> JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> MEDICAL DIAGNOSIS SUPPORT DEVICE   <pre> graph TD     15["yes button"] --- 3["micro controller"]     16["no button"] --- 3     3 --- 5["speech generator"]     3 --- 6["AMPLIFIER"]     3 --- 9["OPTICAL DISPLAY"]     5 --- 6     6 --- 7["Speaker"]     3 --- 4[" "]       </pre> <b>(57) Abstract</b> <p>A device for supporting medical diagnosis of pocket size or wearable on the body comprises a microprocessor (3) programmed for performing a first function of collecting data regarding symptoms of a patient, a user interface (5, 6, 7, 9) connected to the microprocessor (3) for bringing instructions regarding data to be collected into human perceptible form, and a control means (15, 16; 50, 51; 56-58) for inputting the data. The device is also adapted for performing a second, day-to-day function. In operating condition, the first function is permanently and directly activable in response to an operation by the user. By incorporating a device for supporting medical diagnosis in a pocket size or wearable device fulfilling another day-to-day need, the likelihood that the support is directly available in the event of an incident is increased substantially.</p>		

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EE	Estonia						

TITLE: Medical diagnosis support device

FIELD AND BACKGROUND OF THE INVENTION

The invention relates to a device for supporting medical diagnosis. From practice various appliances are known to help medical and paramedical personnel in performing first aid assistance, such as resuscitation in the event of a cardiac arrest. However, such devices do not contribute to solving the problem of providing instantaneous support after an incident or symptoms have occurred, but have to be brought to the patient first. For example, about one-third of the deaths in North America are caused by heart attacks and more than half of these were dead on arrival at a hospital. Even if only a small proportion of these deaths could be prevented by prompt Cardiopulmonary Resuscitation (CPR) a large number of deaths could be prevented. CPR can also save lives in cases of drowning, suffocating, electrocution and drug overdose ("First Aid Handbook" by Alton L. Thygerson, Jones and Bartlett Publishers, 1994, ISBN 0-86720-846-5 and 0-86720-943-7).

20

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a solution which allows to increase the likelihood that adequate diagnosis support is provided in due time in the event of an accident or illness.

According to the invention, this object is achieved by providing a device for supporting first aid assistance in accordance with claim 1.

30 The invention is based on the insight, that if a device for supporting medical diagnosis is incorporated in a pocket size or wearable device fulfilling another day-to-day function, such as knowing the time, keeping keys together or providing telecommunication facilities, which type of device is usually taken along by the user in at least very many

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occasions anyway, and such devices are worn by an important number of people in a given area, the likelihood that, in the event of an incident or illness in that area, support for medical diagnosis is directly available, is increased  
5 substantially.

In particular if, in addition, support for first aid treatment is provided, first aid can not only be provided more adequately by persons having relatively little experience or expertise, but such persons are also reassured,  
10 so that hesitation to help, which often occurs, can be overcome in many cases.

By providing that the data regarding clinical symptoms of the victim are inputted by the user, the need of costly, vulnerable and large input transducers is avoided.

15 Particularly advantageous embodiments of the invention are set forth in the dependent claims.

Further objects, features and advantages of the present invention appears from the detailed description of preferred and other embodiments which is set forth below and in which  
20 reference is made to the drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a frontal view of a device according to the  
25 invention in the form of a wrist watch,

Fig. 2 is a schematic representation of the device according to Fig. 1,

Fig. 3 is a flow chart representing an example of an algorithm programmed in the device according to Figs. 1 and  
30 2,

Fig. 4 is a frontal view of a second example of a device according to the invention in the form of a key-fob, and

Fig. 5 is a frontal view of a third example of a device  
35 according to the invention in the form of a mobile telephone.

#### MODES FOR CARRYING OUT THE INVENTION

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First, the embodiment shown in Figs. 1 and 2 and the algorithm shown in Fig. 3 are described in more detail.

The wristwatch shown in Fig. 1 is adapted to fulfil the function of a device for supporting first aid in emergency situations. The wristwatch comprises a casing 1 which is wearable on the body by means of a metal bracelet 2.

In the casing 1 a microprocessor structure 3 is provided which includes a commercially available IC-chip 4 which is programmed for generating instructions for providing first aid treatment to injured or ill human beings. The hardware programmed control structure may also be provided in other forms, such as for example in the form of a GAL.

To communicate these instructions to a user, a user interface is provided in the form of a speech generator 5 (a commercially available speech chip) which is connected to the microprocessor structure 3 for transferring the instructions into human audible form. For amplifying the speech signal, an amplifier 6 is connected to a mini-loudspeaker 7 for transducing the electrical drive signals from the amplifier 6 into sound. The loudspeaker 7 is located in a section 8 of the casing 1.

In addition, a further user interface is provided in the form of an optical display structure 9 having an optical display 10 (Fig. 1).

In general, providing the instructions in audible form and more in particular in spoken form is generally preferable over providing the instructions in visible or human readable form, since it allows the user to concentrate more fully on the victim. However, in noisy environments or in the event the user has not heard the audible instructions for other reasons, he or she can refer to the optical display to learn the instructions which would otherwise have been missed.

In normal day-to-day use, the shown device functions as a conventional wristwatch. To this end, the microcontroller 3 (which also includes a clock to synchronize its operation) is

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operative to display the time and the date on the optical display 10.

To activate and control the function of supporting first aid, the shown wristwatch is further provided with a "yes" button 15 and a "no" button 16 which are connected to the microcontroller 3 as well. In addition, the watch is provided with first, second third and fourth function buttons 11, 12, 13, 14. By operating the first function button 11, a diagnosis and treatment protocol for providing first aid to suddenly unconscious adult persons not suffering from hypothermia can be started. This protocol is described in more detail hereinafter with reference to Fig. 3. By operating the second button 12, a diagnosis and treatment protocol for providing first aid to patients suffering from breathing problems can be started. The third button 13 is a reset and return button. The fourth button 14 is a scroll button for scrolling between different menu's in which the other buttons have temporary other functions, for example for setting an alarm or for switching between languages or diagnosis protocols.

Since the shown wristwatch performs the function of showing the time, which function is widely appreciated in day-to-day life, the user can easily incorporate the daily use of the device in his normal behaviour, in which the user will generally be used to wearing a wristwatch anyway. Moreover, taking the device along does not require taking along an additional device which is cumbersome. Furthermore, such an additional device is easily lost or forgotten.

By incorporating the use of the medical diagnosis support device in daily life, it is assured that the device is virtually always immediately at hand in the, typically unexpected, event it is needed. In particular if a patient suffering from cardiac arrest is encountered, every second of delay is of vital importance, because the brains of the patient immediately start to suffer from lack of oxygen which often leads to permanent brain damage and the resulting loss of memory or motoric skills or even the death of the victim.

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The algorithm shown in Fig. 3 is started if the first function button 11 is pressed. The start of the algorithm is designated as step 17. In the shown wristwatch, the programming of the microprocessor structure 4 is stored in 5 circuits of the microprocessor structure. Thus, the programming is not lost if batteries are empty or changed and the function of first aid support is always directly activable with no perceptible delay.

By using a programmable read only memory, commercially 10 available standard components can be used to obtain a microprocessor structure having the desired characteristics.

It is also noted that different protocols of the type on which the present algorithm is based are well known in the art in various forms. Reference is made to: "First Aid 15 Handbook" by Alton L. Thygerson, Jones and Bartlett Publishers, 1994, ISBN 0-86720-846-5 and 0-86720-943-7. The present algorithm is described to illustrate the function the shown device fulfils in carrying out such a protocol.

First, the audible and visible message "talk to victim" 20 and the question "Reaction?" are generated repeatedly at step 18 until either the "yes" button or the "no" button is pressed. These messages are simultaneously displayed as is shown in Fig. 1. In response to pressing the "yes" button 15, as is designated by step 19, the algorithm then continues 25 with a section 20 dealing with re-activating or maintaining the patient's breathing. Protocols for re-activating or maintaining a patient's breathing are well known in the art. Therefore this section 20 of the algorithm is not described in more detail than appears from the flow chart.

30 If the response "no" has been entered by pressing the respective button 16 (step 21), the next audible and visible instruction which is generated is "Give pain stimulus". Again, the question "Reaction?" is generated too and simultaneously displayed (step 22).

35 The device is responsive to pressing of the "yes" or the "no" button by generating an audible "yes" or, respectively "no" confirmation and by activating a LED in the

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respective button. By operating the reset and return button 13, the user can make one step back in the algorithm as is designated for example by the "Reset" arrows in Fig. 3. At each stage, operating the reset and return button 13 allows  
5 the user to step back through the algorithm, for example to correct erroneous entries.

If the "yes" button 15 is pressed (step 23), the algorithm continues with the same first step of the section 20 which followed the "yes" response to the question whether  
10 the patient reacted to being spoken to.

If the entered response is again "no" (step 24), the audible and visible instruction "check pulse rate" is generated at step 25. At this occasion the audibly generated and simultaneously visually displayed question is "Pulse  
15 present?". This latter question is in fact a double-check of the victim's condition to verify that the victim is indeed suffering of cardiac arrest so that cardiac massage can be given without adversely affecting a functioning heart. If it is found by the user that, in spite of the previous negative  
20 findings, the victim nevertheless has a pulse, and the "yes" button 15 is operated accordingly (step 26), the algorithm again continues with the same first step of the section 20 which followed the "yes" response to the question whether the patient reacted to being spoken to. If the "no" button 16 is  
25 operated (step 27), the device immediately responds with the instruction "call 1-1-2 (or any other pre-programmed alarm number), start Cardiopulmonary Resuscitation" and the question "One helper?" (step 28).

If the response "no" is entered by pressing the "no" button 16 (step 29), the instruction "five compressions and  
30 one breath" is generated and displayed and, immediately, pulses at a frequency of 80-100 and preferably 90 1/min are generated for cardiac massage (step 30). Simultaneously a red LED incorporated in the "no" button 16 flashes at the same  
35 frequency. Since the LEDs are provided at the front of the watch, these are easily visible during cardiac massage.



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Thus, one helper can carry out the cardiac massage at a frequency indicated by the sounds generated by the watch. Each time five strokes have been counted and completed, the other helper can carry out one mouth-to-mouth resuscitation  
5 breathing.

If the response to the question "One helper?" is "yes" (step 31), then the instruction "fifteen compressions and two breaths" is generated and displayed and, immediately, pulses at a frequency of 80-100 and preferably 90 1/min are  
10 generated for cardiac massage (step 32). Simultaneously a red LED incorporated in the "no" button 16 flashes at the same frequency.

After the cycles for cardiac massage and mouth-to-mouth resuscitation have been indicated for 60 seconds, at step 33,  
15 the instruction "Check pulse" and the question "Pulse present?" are generated like at step 25. If a response "yes" is entered, the programme continues with step 26 which has been discussed before. A small but significant portion of stopped cardiac functions can be recovered by such a short  
20 cardiac massage and further cardiac massage would generally only do harm to the recovered cardiac function.

If the response "no" has been entered (step 34), signifying that the pulse has not been recovered after 60 seconds of heart massage, the cardiac arrest is generally of  
25 a type which typically cannot be reverted by commonly available means and the cardiac massage and mouth-to-mouth resuscitation have to be continued until external help has arrived to limit brain damage due to lack of oxygen.

Accordingly, the instruction "Continue CPR" is generated  
30 (step 35). If after 10 minutes no external help has arrived with instruments, successful resuscitation becomes less and less likely. Optionally signals to this effect can be given. Of course the helper should stop CPR or at least cardiac massage if the victim shows any sign of recovery, otherwise  
35 the heart of which the function is recovering would be adversely affected by the further massage. To obtain guidance for further treatment, the first button 11 can be pressed two

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times. once for stopping the running algorithm and once for restarting the diagnosis protocol to take into account the changed condition of the victim.

By including a diagnosis protocol interactively  
5 responsive to inputted responses, and by operatively  
connecting the microprocessor structure to the control  
buttons for inputting the responses, the user is  
substantially helped to follow a generally accepted diagnosis  
protocol to determine whether CPR is appropriate in the  
10 situation at hand. This helps users to take the right action  
and encourages users, who typically have not encountered the  
need to carry out resuscitation before, overcome hesitation  
and unsureness and to try to help the victim as much as they  
can.

15 The system may be refined to for example to select  
different diagnosis strategies and different manners of  
resuscitation for children and babies. The frequency of the  
signals indicating the rhythm of cardiac massage is for  
instance preferably 100 signals per minute for children and  
20 120 signals per minute for babies.

In particularly persons who have had CPR training, but  
who are normally never required to perform Cardiopulmonary  
Resuscitation except if confronted with such a situation by  
hazard, have great difficulties in maintaining the right pace  
25 during cardiac massage. Thus, providing a device which is  
activable to generate a sequence of signals at a frequency of  
75-140 1/min and preferably at least three selectable  
sequences of signals at frequencies of 80-100, 95-105 and  
115-125 1/min are important to help carrying out cardiac  
30 massage more effectively. In addition, the availability of  
guidance with respect to the frequency of cardiac massage  
reassures persons in a typically stressful situation in which  
cardiac massage to be carried out.

The device according to the present example provides a  
35 particularly effective support, because the microprocessor  
structure 4 is programmed to automatically switch to the  
sequence of signals to support cardiac massage in response to

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particular responses which indicate that cardiac massage is appropriate.

The present invention is not limited to the above described example and many variations are conceivable within  
5 the framework of the present invention. The programming of the device may for example contain algorithms based on protocols for the diagnosis or first aid treatment of many other illnesses and incidents, although the watch is particularly useful to identify situations in which quick  
10 action is advantageous, such as loss of blood, shock or (acute) asthma. A device according to the invention in which a wide range of diagnostic protocols is programmed is for instance particularly useful for members of medical personnel who are frequently confronted with patients having more or  
15 less sudden symptoms. In such cases preliminary measures, quick collection of the appropriate data or just the ability to give a preliminary answer before diagnosis by a specifically consulted doctor can provide important relief. Other persons for whom the device according to the invention  
20 is particularly useful are persons having relatives, roommates or the like suffering from heart and other diseases.

The display may be adapted to display symbols in addition to or instead of alphanumeric characters as is shown  
25 in the examples. The display may also be adapted to show moving images demonstrating actually showing how the diagnosis or treatment. To this end, the display can for example be provided in the form of an LCD display.

Instead of as watch including a clock and a display for  
30 displaying the time of the day, a device according to the invention may also be provided in a form in which its housing forms a key-fob 48 for performing the second, day-to-day function by keeping keys together. In the shown example, the key-fob is provided with a display and "yes" and "no" buttons  
35 50, 51.

In addition to or instead of in the form of buttons, the control means can also be provided in the form of voice

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control, so that the helpers has both hands free while carrying out the diagnosis.

Another option is to provide the device according to the invention in the form of a mobile telephone 52 for  
5 performing the second, non-medical day-to-day function by providing portable telecommunication. A particular advantage of providing a device according to the invention in the form of a mobile telephone is, that use can be made of the  
10 loudspeaker 53 of the telephone 52 to generate the spoken instructions and that the telephone can also be used to automatically search external assistance and to automatically repeat collected data in spoken form to the contacted assistance centre.

Furthermore, also a display 55 and "yes" and "no"  
15 buttons 56, 57 are typically provided in most mobile telephones. To activate the first aid support function, preferably a large button 58 is provided in a prominent position.

Yet another example of a device according to the  
20 invention are an electronic organizer, an electronic dictionary and a calculator in which a medical diagnosis protocol is programmed. In general, pocket size devices preferably fit within a box having internal dimensions of 16 x 6 x 3 cm or less and a wearable device is preferably  
25 provided with a clip, a strap or a string to suspend the device to the body or to a piece of clothing worn by the user.

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CLAIMS

1. A device for supporting first aid in emergency situations comprising:

a housing (1; 48) of pocket size or wearable on the body,

5 a microprocessor structure (3) programmed with a diagnosis protocol for performing a first function of generating instructions indicating data regarding symptoms of a patient to be collected and for collecting entered data,

a user interface operatively (5, 6, 7, 9) connected to  
10 said microprocessor structure (3) for bringing said instructions into human perceptible form, and

at least one user operable control means (15, 16; 50, 51; 56-58) operatively connected to said microprocessor structure (3) for inputting said data regarding symptoms of a  
15 patient by said user operable control means (15, 16; 50, 51; 56-58),

said device further being adapted for performing a second, day-to-day function other than said first function, and said first function being permanently and directly  
20 activable by said at least one user operable control means (15, 16; 50, 51; 56-58).

2. A device according to claim 1, wherein said microprocessor structure (3) is programmed for generating instructions for treatment of ill or injured human beings in  
25 accordance with entered data regarding symptoms of a patient and said diagnosis protocol.

3. A device according to claim 1 or 2, wherein said microprocessor structure (3) is programmed for generating instructions for first aid treatment of ill or injured human  
30 beings in accordance with entered data regarding symptoms of a patient and said diagnosis protocol.

4. A device according to claim 3, wherein said first aid instructions include at least a sequence of signals at a frequency of 75-140 1/min.

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5. A device according to claim 3 or 4, wherein said microprocessor structure (3) is programmed such that said first aid instructions include at least three selectable sequences of signals at frequencies of 80-100, 95-105 and  
5 115-125 1/min.

6. A device according to claim 4 or 5, wherein said signals include at least human audible signals.

7. A device according to claim 4-6, wherein said microprocessor structure (3) is programmed to automatically  
10 switch to said at least one sequence of signals in response to at least one type of inputted response.

8. A device according to any one of the preceding claims, wherein said programming of said microprocessor structure (3) is stored in circuits of said microprocessor  
15 structure (3).

9. A device according to claim 8, wherein said microprocessor structure (3) includes a programmable read only memory (4).

10. A device according to any one of the preceding  
20 claims including a speech generator (5) for providing at least a portion of said instructions in spoken form.

11. A device according to any one of the preceding claims including a clock and a display for performing said second, day-to-day function by displaying at least the time  
25 of the day.

12. A device according to any one of the preceding claims wherein said housing (48) forms a key-fob for performing said second, day-to-day function by keeping keys together.

30 13. A device according to any one of the preceding claims including a mobile telephone for performing said second, day-to-day function by providing portable telecommunication.

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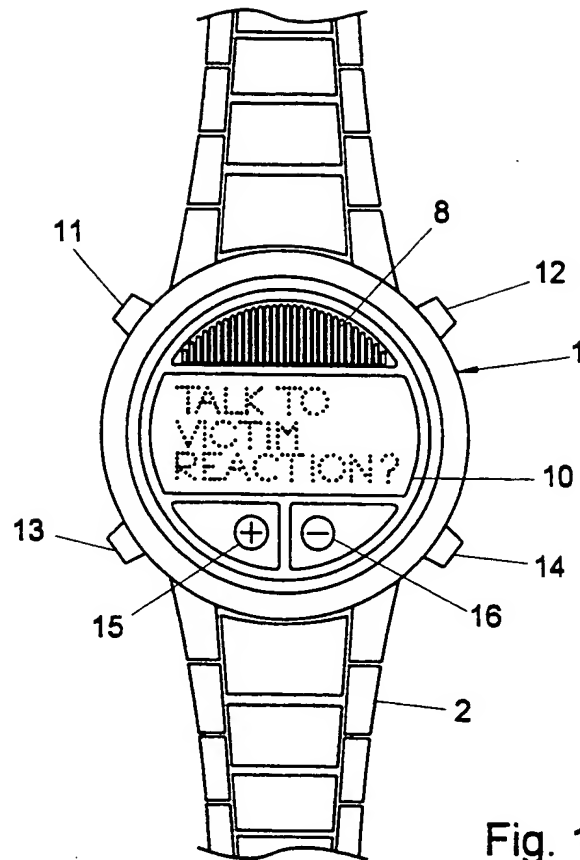


Fig. 1

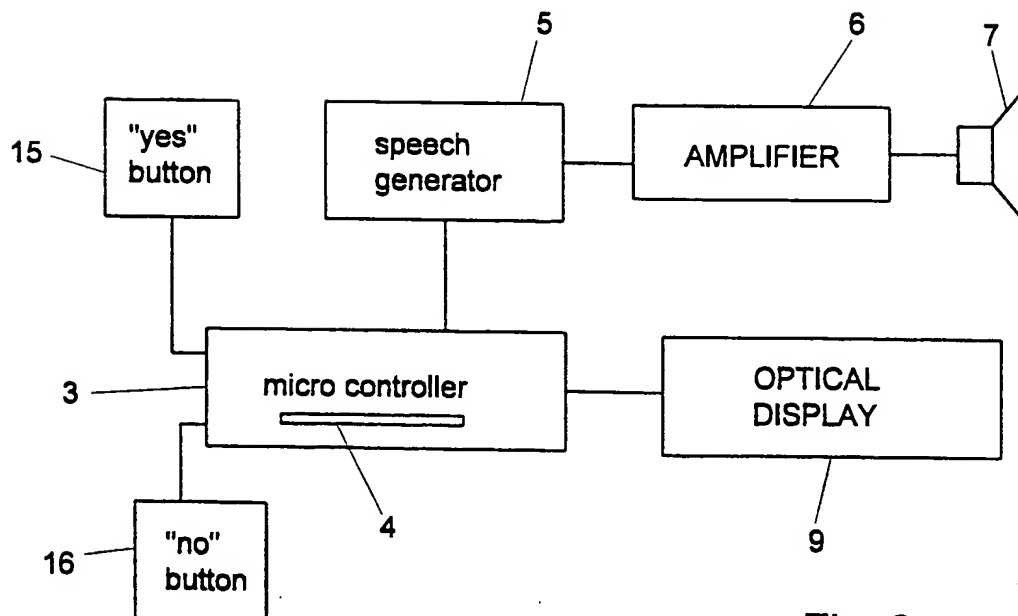


Fig. 2

**SUBSTITUTE SHEET (RULE 26)**

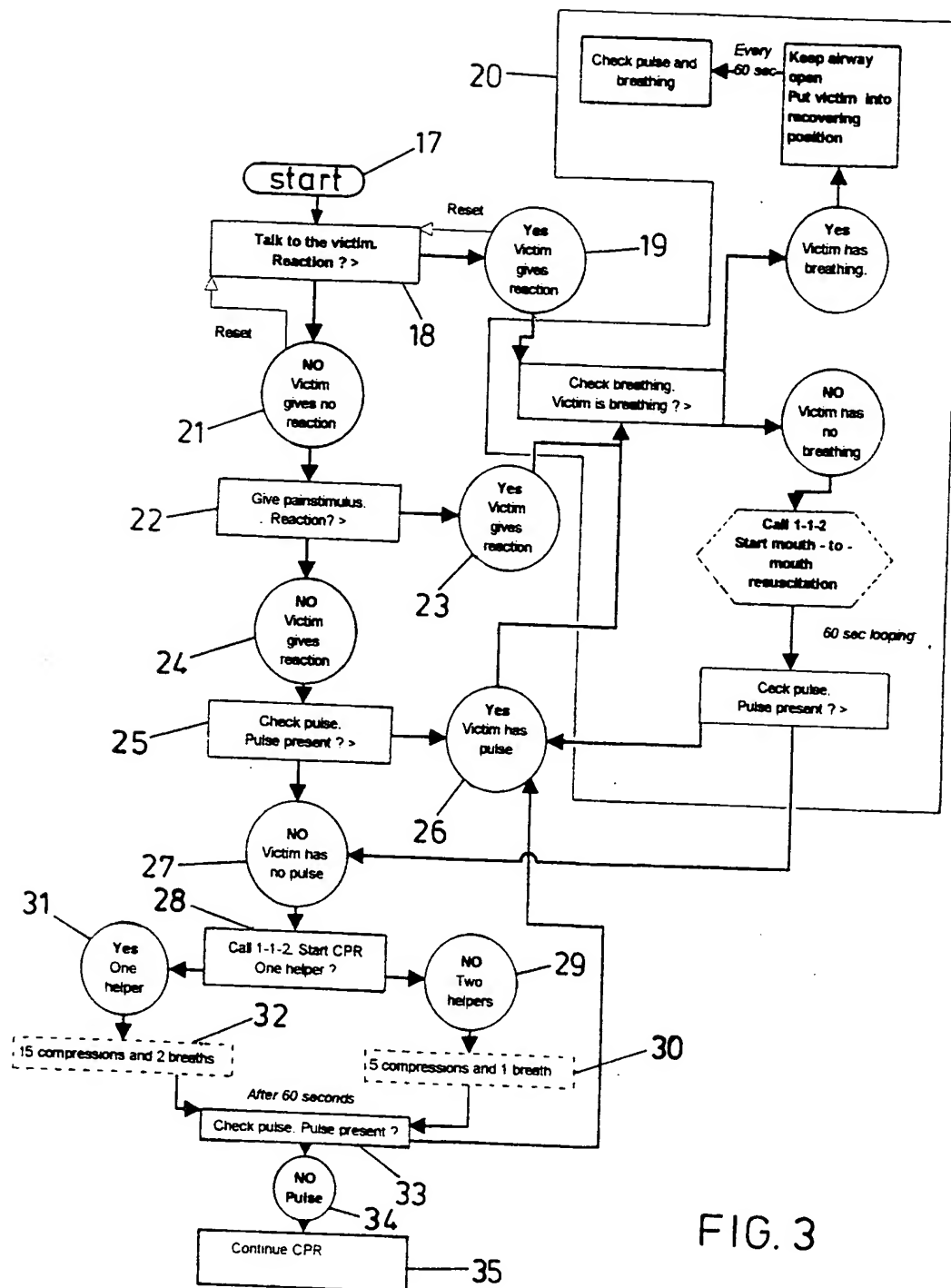


FIG. 3

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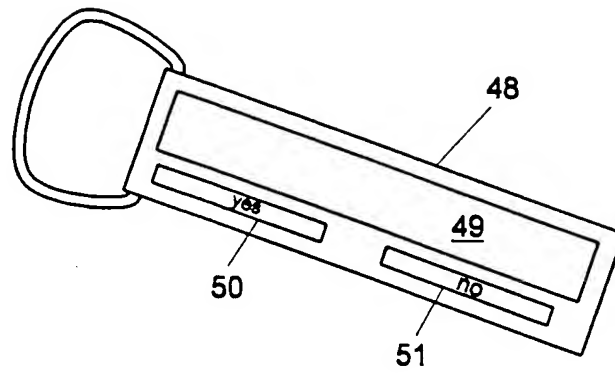


Fig. 4

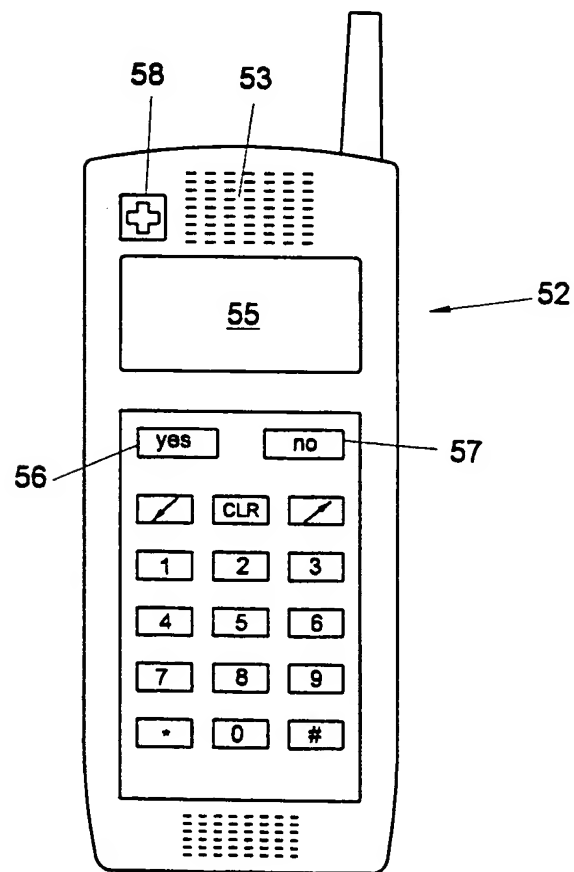


Fig. 5

**SUBSTITUTE SHEET (RULE 26)**

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 97/00315

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 086 391 A (CHAMBERS) 4 February 1992 see the whole document ---	1-3,8-10
A	US 4 863 385 A (PIERCE) 5 September 1989 see column 3, line 18 - column 10, line 31 ---	1,3-7,9
A	US 5 088 037 A (BATTAGLIA) 11 February 1992 see column 3, line 11 - column 6, line 2 ---	1-3,8,9
A	WO 95 00939 A (STUDER) 5 January 1995 see the whole document ---	1,11
A	FR 2 611 948 A (LEVY & KRAFFE) 9 September 1988 see page 5, line 7 - page 7, line 15 ---	1,12
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

13 February 1998

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20/02/1998

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# INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 06490 A (OMNIPOINT CORPORATION) 29 February 1996 see page 155, paragraph 3 -----	1, 13

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Information on patent family members

International Application No

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